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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,158	08/02/2007	Alan McLeod	175US1	2164
30328	7590	05/10/2010		
NuVasive c/o CPA Global P.O. Box 52050 Minneapolis, MN 55402			EXAMINER BECCIA, CHRISTOPHER J	
			ART UNIT 3775	PAPER NUMBER
			MAIL DATE 05/10/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,158	Applicant(s) MCLEOD ET AL.	
	Examiner CHRISTOPHER BECCIA	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 7-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 7-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. As to Claim 21, Applicant argues that Ferree fails to disclose a method that includes "connecting the first portion to the second portion at one or more locations using the variable link, the variable link passing through the material." Examiner respectfully disagrees. Examiner contends that the variable link 114 passes *through* the annulus (the material), as it links the inner arms of the implant with the outer wall. The position of link 114 as seen in Fig. 2 does disclose a variable link that passes through the material.
2. Applicant's arguments with respect to claims 1, 3-5, 7-20, and 22-24 have been considered but are moot in view of the new ground(s) of rejection. Please direct attention to rejection below, specifically reference Trieu as to teach a common element folded into a plurality of portions.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

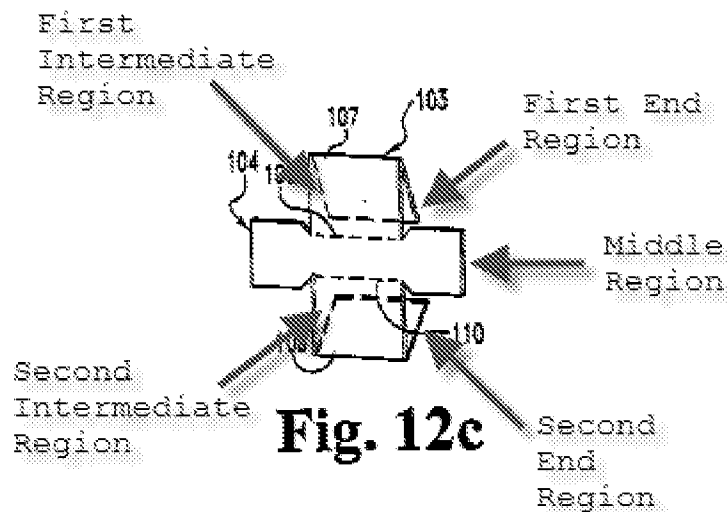
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claims 1, 5, 7-11, 15, 17, and 21-23** are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Pub. No. 2004/0039392 to *Trieu*.

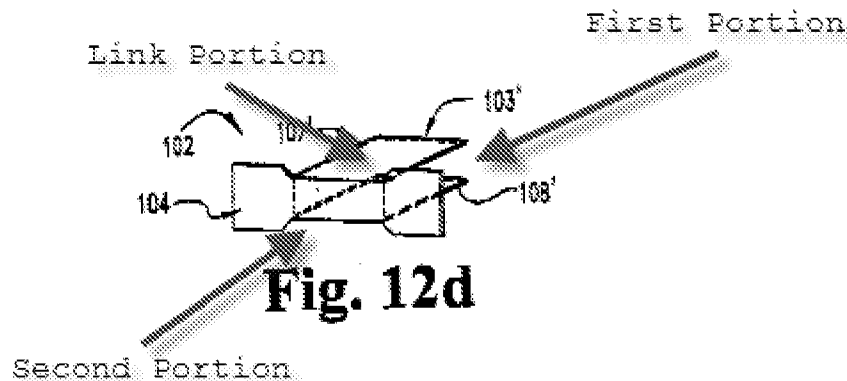
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As to **Claim 1**, *Trieu* discloses a fissure repair device (Figs. 12a-12f) comprising:

a common element (100) folded into a plurality of portions (Fig. 12c), the common element having a first end region and a second end region, separated by a middle region, the first end region and middle region further separated by a first intermediate region, the second end region and middle region further separated by a second intermediate region (See Fig. 12c Below),



the device including a first portion, a second portion, the first portion being formed by both end regions of the element and link portions formed by the first and second intermediate regions (Fig. 12d below); and



a variable link between the first portion and second portion (length of 107 and 108 can be varied depending on length of element 100).

As to **Claim 5**, *Trieu* discloses a fissure repair device wherein each of the first and second end portions is provided with one or more areas of reinforcement (103', [0061])

As to **Claim 7**, *Trieu* discloses a fissure repair device wherein the link portion includes one or more materials which promote tissue in growth and/or the supply of blood [0029].

As to **Claim 8**, *Trieu* discloses a fissure repair device wherein a first fold (109) is provided between the middle region and the first intermediate region, a second fold (110) is provided between the middle region and the second intermediate region, a third fold (near 107, Fig. 12c) is provided between the first intermediate region and the first end region, and a fourth fold (near 108, Fig. 12c) is provided between the second intermediate region and the second end region (folds seen in Figs. 12c and 12d).

As to **Claim 9**, *Trieu* discloses a fissure repair device wherein, when folded, the first intermediate region contacts the second intermediate region (via 106) and the first and second intermediate regions are substantially parallel to one another (Fig. 12e).

As to **Claim 10**, *Trieu* discloses a fissure repair device wherein the first intermediate region is at $90^{\circ} \pm 5^{\circ}$ to at least one of the first end region and the middle region (during folds 12b-12c, [0061]).

As to **Claim 11**, *Trieu* discloses a fissure repair device wherein at least one of the first and second intermediate regions contact a side of the fissure (Fig. 12f, and [0061]).

As to **Claim 15**, *Trieu* discloses a fissure repair device wherein a receiving space for the annulus to one side of the fissure is provided between first end region of the first portion and the second portion and a receiving space for the annulus to the other side of the fissure is provided between the second end region of the first portion and the second portion (Fig. 12f, and [0061]).

As to **Claim 17**, *Trieu* discloses a fissure repair device wherein a second portion (Fig. 12d above) includes a plurality of inclined barbs (20) to provide anchoring to the annulus [0033].

As to **Claim 22**, *Trieu* discloses a fissure repair device wherein a further fold is provided at least one of between a first part of the first end region and a second part of the first end region and between a third part of the first end region and a second part of the first end region (103').

As to **Claim 23**, *Trieu* discloses a fissure repair device wherein the second intermediate region is at $90^{\circ} \pm 5^{\circ}$ to at least one of the second end region and the middle region (Fig. 12d).

3. **Claims 21** is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Pub. No. 2003/0078579 to *Ferree*.

As to **Claim 21**, *Ferree* discloses a method of repairing a fissure in a material, the method including the steps of: providing a fissure repair device [0039], the device including a first portion (110 and 110'), a second portion (120 and 120') and a variable link (114); deploying the first portion of the device inside the fissure [0044]; deploying the second portion of the device outside the fissure (Fig. 7D); connecting the first portion to the second portion at one or more locations using the variable link [0042, 0044], the variable link passing through the material (See Fig. 2 and Fig. 7D).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 3 and 4** are rejected under 35 U.S.C. 103(a) as being unpatenable over U.S. Patent Pub. No. 2003/0078579 to *Trieu* in view of U.S. Patent No. 7,341,601 to *Eisermann et al.*

As to **Claims 3 and 4**, *Trieu* discloses the claimed invention except wherein the first portion includes a first part, second part and third part, the first portion being provided with one or more holes in the second part thereof, the first portion being provided in the first and third parts thereof with one or more further sets of holes; and at least one of the first part and third part is folded against the second part, the holes in the first and third parts align with holes in the second part.

Eisermann discloses a fissure repair device (30 in Fig. 6) wherein the first portion being provided with one or more holes in the second part thereof (holes within mesh of 30 and 35a and b), the first portion being provided in the first and third parts thereof with one or more further sets of holes (holes provide through portions of implant in Fig. 6); and the first part and/or third part are folded against the second part, the holes in the first and third parts align with holes in the second part (folding over in 30 in Fig. 6 would align 35a, b, and holes within mesh) in order to promotes tissue growth and repair of the annulus and stabilize the implant (Col. 2, lines 36-50).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fissure repair device of *Trieu* with the holes of *Eisermann* in order to promotes tissue growth and repair of the annulus and stabilize the implant.

6. **Claims 12-14, 16, 18-20, and 24** are rejected under 35 U.S.C. 103(a) as being unpatenable over U U.S. Patent Pub. No. 2004/0039392 to *Trieu* in view of U.S. Patent Pub. No. 2003/0078579 to *Ferree*.

As to **Claims 12-14, 16, 18-20, and 24** *Trieu* discloses the claimed invention except for wherein the first portion and second portion define the verticals of an H shape, particularly when considered in plan view in an intervertebral disc space, and the link portion defines the cross bar of an H shape; wherein at least two variable links are provided, a first variable link provided between the first end region and the second portion and a second variable link provided between the second end region and the second portion; wherein a variable link is used to one or more of vary the distance between one end region of the first portion and the second portion, vary the tension between one region end of the first portion and the second portion, pull the first portion against the inside of the annulus or a part thereof, and pull the second portion against the outside of the annulus; wherein the link portion passes through the fissure, from the inside of the annulus to the outside thereof and the link portion keeps the sides of the fissure apart; in which the first end region is provided with a reduced height neck part and the second end region is provided with an aperture; wherein the first intermediate region is provided with a reduced height neck part and the second intermediate region is provided with an aperture; wherein the first intermediate region provided with the reduce height neck part is passed through the aperture in the second intermediate region; wherein the first end region provided with the reduced height neck part is passed through the aperture in the second end region.

Ferree discloses a fissure repair device (15) including a first portion (110 and 110'), a second portion (120 and 120') and a variable link (114) between the first portion and second portion, the first portion being linked to the second portion by one

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or more link portions (114), the second portion being formed by both end portions of the element [0042] and (Fig. 4 shows 120 and 120' at end portion of element); wherein the first portion and second portion define the verticals of an H shape, particularly when considered in plan view in an intervertebral disc space, and the link portion defines the cross bar of an H shape (Figs. 1 and 2); wherein a variable link is used to one or more of vary the distance between one end region of the first portion and the second portion, vary the tension between one region end of the first portion and the second portion, pull the first portion against the inside of the annulus or a part thereof, and pull the second portion against the outside of the annulus [0041, 0042]; in which the first portion (110 and 110') is in the forming of a first second portion (120) forming part, first link portion (114), first portion (110 and 110'), second link portion (108) and second portion forming part (120'), with this being the sequence from one end to the other of the element; in which one of the second portion forming parts (120) and/or the link portion (140) connected to it, is provided with a reduced height part and/or neck part (neck part in [0042]) and the other of the second portion forming parts (120') and/or the link portion connected to it, is provided with an aperture (aperture through 108 surrounding 114); in which the second portion forming part provided with the reduced height part and/or neck part is passed through the hole in the other second portion forming part [0042] in order to provide an intradiscal component is typically positioned adjacent the inner surface of the annulus fibrosis, with the invention further including a body disposed between the intradiscal and extradiscal components to at least partially consume the defect [0012].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fissure repair device of *Trieu* with the shape and link modifications of *Ferree* in order to provide an intradiscal component is typically positioned adjacent the inner surface of the annulus fibrosis, with the invention further including a body disposed between the intradiscal and extradiscal components to at least partially consume the defect.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BECCIA whose telephone number is (571)270-7391. The examiner can normally be reached on M-F 7:30am - 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775